# Exhibit 167
# (Filed Under Seal)

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., MERZ PHARMA GMBH & CO. KGAA, and MERZ PHARMACEUTICALS GMBH,<br><br>Plaintiffs,<br><br>v.<br><br>DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES LIMITED, GENPHARM INC., GENPHARM, L.P., INTERPHARM HOLDINGS, INC., INTERPHARM, INC., MYLAN PHARMACEUTICALS INC., RANBAXY INC., RANBAXY LABORATORIES LIMITED, KENDLE INTERNATIONAL INC., SUN INDIA PHARMACEUTICAL INDUSTRIES LIMITED (a/k/a SUN PHARMACEUTICAL INDUSTRIES LTD.), SYNTHON HOLDING B.V., SYNTHON B.V., SYNTHON LABORATORIES, INC., and SYNTHON PHARMACEUTICALS, INC.,<br><br>Defendants. | C.A. No. 08-52 (GMS) |

**AMENDED COMPLAINT**

Plaintiffs Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively "Plaintiffs") for their Complaint against Defendants Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories Limited, Genpharm Inc., Genpharm, L.P., Interpharm Holdings, Inc., Interpharm, Inc., Mylan Pharmaceuticals Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited, Kendle International Inc., Sun India Pharmaceutical Industries Ltd. (a/k/a Sun Pharmaceutical Industries Limited), Synthon

Holding B.V., Synthon B.V., Synthon Laboratories, Inc., and Synthon Pharmaceuticals, Inc. (collectively "Defendants") hereby allege as follows:

**PARTIES**

1. Plaintiff Forest Laboratories, Inc. ("Forest Labs") is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

2. Plaintiff Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda (referred to herein, together with Forest Laboratories, Inc., as "Forest").

3. Plaintiff Merz Pharma GmbH & Co. KGaA is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany.

4. Plaintiff Merz Pharmaceuticals GmbH is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany (referred to herein, together with Merz Pharma GmbH & Co. KGaA, as "Merz").

5. Upon information and belief, Defendant Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's Labs") is a New Jersey corporation, and the wholly-owned subsidiary and agent of Dr. Reddy's Laboratories Limited, having a principal place of business at 200 Somerset Corporate Boulevard, Building II, Bridgewater, New Jersey 08807. Upon information and belief, Defendant Dr. Reddy's Labs manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

6. Upon information and belief, Defendant Dr. Reddy's Laboratories Limited ("Dr. Reddy's Limited") is an Indian corporation having a principal place of business at 7-1-27 Ameerpet, Hyderabad 500 016, India. Upon information and belief, Defendant Dr. Reddy's

Limited, itself and through its wholly-owned subsidiary and agent Defendant Dr. Reddy's Labs, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

7. Upon information and belief, Defendant Genpharm, L.P. ("Genpharm LP") is a New York entity, and the sister company and agent of Genpharm, Inc., having a principal place of business at 150 Motor Parkway, Hauppauge, New York 11788. Upon information and belief, Defendant Genpharm LP manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

8. Upon information and belief, Defendant Genpharm Inc. ("Genpharm") is a Canadian corporation having a principal place of business at 85 Advance Road, Etobicoke, Ontario M8Z 2S6, Canada. Upon information and belief, Defendant Genpharm, itself and through its sister company and agent Defendant Genpharm LP, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

9. Upon information and belief, Defendant Interpharm Holdings, Inc. ("Interpharm Holdings") is a Delaware corporation having a principal place of business at 75 Adams Avenue, Hauppauge, New York 11788.

10. Upon information and belief, Defendant Interpharm, Inc. ("Interpharm") is a New York corporation, and the wholly-owned subsidiary and agent of Interpharm Holdings, having a principal place of business at 75 Adams Avenue, Hauppauge, New York 11788. Upon information and belief, Defendant Interpharm, itself and on behalf of its parent and principal Defendant Interpharm Holdings, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

11. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. ("Mylan") is a West Virginia corporation having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26504. Upon information and belief, Defendant Mylan manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

12. Upon information and belief, Defendant Ranbaxy Inc. ("Ranbaxy") is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Ranbaxy Laboratories Limited, having a principal place of business at 600 College Road East, Princeton, New Jersey 08540.

13. Upon information and belief, Defendant Ranbaxy Laboratories Limited ("Ranbaxy Labs") is an Indian corporation having a principal place of business at Plot 90, Sector 32, Gurgaon, Haryana 122 001, India. Upon information and belief, Defendant Ranbaxy Labs, itself and through its wholly-owned subsidiary and agent Defendant Ranbaxy, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

14. Upon information and belief, Defendant Kendle International Inc. ("Kendle") is an Ohio corporation, and an agent of Defendant Sun India Pharmaceutical Industries Limited (a/k/a Sun Pharmaceutical Industries Limited), having a principal place of business at 441 Vine Street, Cincinnati, Ohio 45202.

15. Upon information and belief, Defendant Sun India Pharmaceutical Industries Limited ("Sun India") (a/k/a Sun Pharmaceutical Industries Limited) is an Indian corporation having a principal place of business at Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai, Maharashtra 400 059, India. Upon information and belief, Defendant Sun India

manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

16. Upon information and belief, Defendant Synthon Holding B.V. ("Synthon Holding") is a Dutch entity having a principal place of business at Microweg 22, 6545 CM Nijmegen, Netherlands. Upon information and belief, Defendant Synthon Holding, itself and through its subsidiaries and agents Defendants Synthon B.V., Synthon Laboratories, Inc., and Synthon Pharmaceuticals, Inc., manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

17. Upon information and belief, Defendant Synthon B.V. ("Synthon") is a Dutch entity having a principal place of business at Microweg 22, P.O. Box 7071, 6503 GN Nijmegen, Netherlands. Upon information and belief, Defendant Synthon, itself, on behalf of its parent Defendant Synthon Holding, and through its sister companies and agents Defendants Synthon Laboratories, Inc., and Synthon Pharmaceuticals, Inc., manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

18. Upon information and belief, Defendant Synthon Laboratories, Inc. ("Synthon Labs") is a Virginia corporation having a principal place of business at 7130 Heritage Village Plaza, Suite 201, Gainesville, Virginia 20155. Upon information and belief, Defendant Synthon Labs, itself and on behalf of its parent Defendant Synthon Holding and its sister companies Defendants Synthon and Synthon Pharmaceuticals, Inc., submitted Abbreviated New Drug Application ("ANDA") No. 90-047 to the United States Food and Drug Administration ("FDA"). Upon information and belief, Defendant Synthon Labs, through its parent Defendant Synthon Holding and its sister companies Defendants Synthon and Synthon Pharmaceuticals,

Inc., manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

19. Upon information and belief, Defendant Synthon Pharmaceuticals, Inc. ("Synthon Pharma") is a North Carolina corporation having a principal place of business at 9000 Development Drive, P.O. Box 110487, Research Triangle Park, North Carolina 27709. Upon information and belief, Defendant Synthon Pharma, itself and on behalf of its parent Defendant Synthon Holding and its sister companies Defendants Synthon and Synthon Labs, manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

## NATURE OF THE ACTION

20. This is a civil action for infringement of United States Patent No. 5,061,703 ("the '703 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

## JURISDICTION AND VENUE

21. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

22. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Plaintiff Forest Labs, a Delaware corporation. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

23. This Court has personal jurisdiction over Defendant Dr. Reddy's Labs by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

24. This Court has personal jurisdiction over Defendant Dr. Reddy's Limited by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its subsidiary and agent Dr. Reddy's Labs.

25. This Court has personal jurisdiction over Defendant Genpharm LP by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

26. This Court has personal jurisdiction over Defendant Genpharm by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its sister company and agent Genpharm LP.

27. This Court has personal jurisdiction over Defendant Interpharm Holdings by virtue of the fact that, *inter alia*, Interpharm Holdings is a Delaware corporation.

28. This Court has personal jurisdiction over Defendant Interpharm by virtue of, *inter alia*: (1) its presence in Delaware through its parent and principal Interpharm Holdings; and (2) its systematic and continuous contacts with Delaware, including through its parent and principal Interpharm Holdings.

29. This Court has personal jurisdiction over Defendant Mylan by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

30. This Court has personal jurisdiction over Defendant Ranbaxy by virtue of the fact that, *inter alia*, Ranbaxy is a Delaware corporation.

31. This Court has personal jurisdiction over Defendant Ranbaxy Labs by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Ranbaxy; and

(2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Ranbaxy.

32. This Court has personal jurisdiction over Defendant Kendle by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

33. This Court has personal jurisdiction over Defendant Sun India by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

34. This Court has personal jurisdiction over Defendant Synthon Holding by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its subsidiaries and agents Synthon, Synthon Labs, and Synthon Pharma.

35. This Court has personal jurisdiction over Defendant Synthon by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its parent Synthon Holding and its sister companies and agents Synthon Labs and Synthon Pharma.

36. This Court has personal jurisdiction over Defendant Synthon Labs by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its parent Synthon Holding and its sister companies Synthon and Synthon Pharma.

37. This Court has personal jurisdiction over Defendant Synthon Pharma by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its parent Synthon Holding and its sister companies Synthon and Synthon Labs.

38. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**THE PATENT-IN-SUIT**

39. On October 29, 1991, the '703 patent, titled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia," was duly and legally issued by the United

States Patent and Trademark Office ("PTO"). Merz has been, and continues to be, the sole assignee of the '703 patent since its issuance.

40. Forest is the exclusive licensee of the '703 patent in the United States. Forest holds New Drug Application ("NDA") No. 21-487 for Namenda® brand memantine hydrochloride tablets. The '703 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Namenda®.

41. Forest is the exclusive distributor of Namenda® in the United States.

42. On August 18, 2004, Merz submitted a request to the PTO for reexamination of the '703 patent. The PTO issued a reexamination certificate (Exhibit B) for the '703 patent on November 7, 2006.

## ACTS GIVING RISE TO THIS ACTION

### Count I – Infringement Of The '703 Patent By Defendants Dr. Reddy's Limited And Dr. Reddy's Labs

43. Upon information and belief, Defendant Dr. Reddy's Limited, through its subsidiary and agent Dr. Reddy's Labs, submitted ANDA No. 90-048 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride ("the Dr. Reddy's Generic Products"). ANDA No. 90-048 specifically seeks FDA approval to market the Dr. Reddy's Generic Products prior to the expiration of the '703 patent.

44. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Dr. Reddy's Limited alleged in ANDA No. 90-048 that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or

sale of the Dr. Reddy's Generic Products. Plaintiffs received written notification of ANDA No. 90-048 and its § 505(j)(2)(A)(vii)(IV) allegation on or about January 4, 2008.

45. Dr. Reddy's Limited's submission of ANDA No. 90-048 to the FDA, through its subsidiary and agent Dr. Reddy's Labs, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Dr. Reddy's Limited commercially manufactures, uses, offers to sell, sells, or imports any of the Dr. Reddy's Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

46. Dr. Reddy's Labs is jointly and severally liable for any infringement of the '703 patent. Upon information and belief, Dr. Reddy's Labs participated in, contributed to, aided, abetted and/or induced Dr. Reddy's Limited's submission of ANDA No. 90-048 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

47. Dr. Reddy's Labs' participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 90-048 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Dr. Reddy's Labs commercially manufactures, uses, offers to sell, sells, or imports any of the Dr. Reddy's Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

48. Dr. Reddy's Limited and Dr. Reddy's Labs were aware of the '703 patent prior to filing ANDA No. 90-048.

49. Dr. Reddy's Limited's and Dr. Reddy's Labs' actions render this an exceptional case under 35 U.S.C. § 285.

50. Plaintiffs will be irreparably harmed by Dr. Reddy's Limited's and Dr. Reddy's Labs' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count II – Infringement Of The '703 Patent By Defendants Genpharm And Genpharm LP**

51. Upon information and belief, Defendant Genpharm, through its sister company and agent Genpharm LP, submitted ANDA No. 90-050 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Genpharm's ANDA No. 90-050 seeks FDA approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride ("the Genpharm Generic Products"). Genpharm's ANDA No. 90-050 specifically seeks FDA approval to market the Genpharm Generic Products prior to the expiration of the '703 patent.

52. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Genpharm alleged in ANDA No. 90-050 that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Genpharm Generic Products. Plaintiffs received written notification of ANDA No. 90-050 and its § 505(j)(2)(A)(vii)(IV) allegation on or about December 18, 2007.

53. Genpharm's submission of ANDA No. 90-050 to the FDA, through its sister company and agent Genpharm LP, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Genpharm commercially manufactures, uses, offers to sell, sells, or imports any of the Genpharm Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

54. Genpharm LP is jointly and severally liable for any infringement of the '703 patent. Upon information and belief, Genpharm LP participated in, contributed to, aided, abetted and/or induced Genpharm's submission of ANDA No. 90-050 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

55. Genpharm LP's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 90-050 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Genpharm LP commercially manufactures, uses, offers to sell, sells, or imports any of the Genpharm Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

56. Genpharm and Genpharm LP were aware of the '703 patent prior to filing ANDA No. 90-050.

57. Genpharm's and Genpharm LP's actions render this an exceptional case under 35 U.S.C. § 285.

58. Plaintiffs will be irreparably harmed by Genpharm's and Genpharm LP's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count III – Infringement Of The '703 Patent**
**By Defendants Interpharm And Interpharm Holdings**

59. Upon information and belief, Defendant Interpharm, on behalf of its parent and principal Interpharm Holdings, submitted ANDA No. 90-041 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride ("the Interpharm

Generic Products"). ANDA No. 90-041 specifically seeks FDA approval to market the Interpharm Generic Products prior to the expiration of the '703 patent.

60. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Interpharm alleged in ANDA No. 90-041 that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Interpharm Generic Products. Plaintiffs received written notification of ANDA No. 90-041 and its § 505(j)(2)(A)(vii)(IV) allegation on or about December 19, 2007.

61. Interpharm's submission of ANDA No. 90-041 to the FDA, on behalf of its parent and principal Interpharm Holdings, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Interpharm commercially manufactures, uses, offers to sell, sells, or imports any of the Interpharm Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

62. Interpharm Holdings is jointly and severally liable for any infringement of the '703 patent. Upon information and belief, Interpharm Holdings participated in, contributed to, aided, abetted and/or induced Interpharm's submission of ANDA No. 90-041 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

63. Interpharm Holdings' participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 90-041 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Interpharm Holdings commercially manufactures, uses, offers to sell, sells, or imports any of the Interpharm Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

64. Interpharm and Interpharm Holdings were aware of the '703 patent prior to filing ANDA No. 90-041.

65. Interpharm's and Interpharm Holdings' actions render this an exceptional case under 35 U.S.C. § 285.

66. Plaintiffs will be irreparably harmed by Interpharm's and Interpharm Holdings' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count IV – Infringement Of The '703 Patent By Defendant Mylan**

67. Upon information and belief, Defendant Mylan submitted ANDA No. 79-225 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Mylan's ANDA No. 79-225 seeks FDA approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride ("the Mylan Generic Products"). Mylan's ANDA No. 79-225 specifically seeks FDA approval to market the Mylan Generic Products prior to the expiration of the '703 patent.

68. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Mylan alleged in ANDA No. 79-225 that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Mylan Generic Products. Plaintiffs received written notification of ANDA No. 79-225 and its § 505(j)(2)(A)(vii)(IV) allegation on or about December 18, 2007.

69. Mylan's submission of ANDA No. 79-225 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan commercially manufactures, uses, offers to sell, sells, or imports any of the Mylan Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

70. Mylan was aware of the '703 patent prior to filing ANDA No. 79-225.

71. Mylan's actions render this an exceptional case under 35 U.S.C. § 285.

72. Plaintiffs will be irreparably harmed by Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count V – Infringement Of The '703 Patent By Defendants Ranbaxy Labs And Ranbaxy**

73. Upon information and belief, Defendant Ranbaxy Labs, through its subsidiary and agent Ranbaxy, submitted ANDA No. 79-236 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride ("the Ranbaxy Generic Products"). ANDA No. 79-236 specifically seeks FDA approval to market the Ranbaxy Generic Products prior to the expiration of the '703 patent.

74. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Ranbaxy Labs alleged in ANDA No. 79-236 that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Ranbaxy Generic Products. Plaintiffs received written notification of ANDA No. 79-236 and its § 505(j)(2)(A)(vii)(IV) allegation on or about December 19, 2007.

75. Ranbaxy Labs' submission of ANDA No. 79-236 to the FDA, through its subsidiary and agent Ranbaxy, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Ranbaxy Labs commercially manufactures, uses, offers to sell, sells, or imports any of the Ranbaxy Generic

Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

76. Ranbaxy is jointly and severally liable for any infringement of the '703 patent. Upon information and belief, Ranbaxy participated in, contributed to, aided, abetted and/or induced Ranbaxy Labs' submission of ANDA No. 79-236 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

77. Ranbaxy's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 79-236 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Ranbaxy commercially manufactures, uses, offers to sell, sells, or imports any of the Ranbaxy Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

78. Ranbaxy Labs and Ranbaxy were aware of the '703 patent prior to filing ANDA No. 79-236.

79. Ranbaxy Labs' and Ranbaxy's actions render this an exceptional case under 35 U.S.C. § 285.

80. Plaintiffs will be irreparably harmed by Ranbaxy Labs' and Ranbaxy's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count VI – Infringement Of The '703 Patent By Defendants Sun India And Kendle**

81. Upon information and belief, Defendant Sun India, through its agent Kendle, submitted ANDA No. 90-058 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial

manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride ("the Sun Generic Products"). ANDA No. 90-058 specifically seeks FDA approval to market the Sun Generic Products prior to the expiration of the '703 patent.

82. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Sun India alleged in ANDA No. 90-058 that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Sun Generic Products. Plaintiffs received written notification of ANDA No. 90-058 and its § 505(j)(2)(A)(vii)(IV) allegation on or about December 20, 2007.

83. Sun India's submission of ANDA No. 90-058 to the FDA, through its agent Kendle, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Sun India commercially manufactures, uses, offers to sell, sells, or imports any of the Sun Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

84. Kendle is jointly and severally liable for any infringement of the '703 patent. Upon information and belief, Kendle participated in, contributed to, aided, abetted and/or induced Sun India's submission of ANDA No. 90-058 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

85. Kendle's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 90-058 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Kendle commercially manufactures, uses, offers to sell, sells, or imports any of the Sun

Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

86. Sun India and Kendle were aware of the '703 patent prior to filing ANDA No. 90-058.

87. Sun India's and Kendle's actions render this an exceptional case under 35 U.S.C. § 285.

88. Plaintiffs will be irreparably harmed by Sun India's and Kendle's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count VII – Infringement Of The '703 Patent By Defendants Synthon Holding, Synthon, Synthon Labs, and Synthon Pharma**

89. Upon information and belief, Defendant Synthon Labs, on behalf of its parent Synthon Holding and its sister companies Synthon and Synthon Pharma, submitted ANDA No. 90-047 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use and sale of generic tablets containing 5 milligrams of memantine hydrochloride ("the Synthon Generic Product"). ANDA No. 90-047 specifically seeks FDA approval to market the Synthon Generic Product prior to the expiration of the '703 patent.

90. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Synthon Labs alleged in ANDA No. 90-047 that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Synthon Generic Product. Plaintiffs received written notification of ANDA No. 90-047 and its § 505(j)(2)(A)(vii)(IV) allegation on or about February 5, 2008.

91. Synthon Labs' submission of ANDA No. 90-047 to the FDA, on behalf of its parent Synthon Holding and its sister companies Synthon and Synthon Pharma, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Synthon Labs commercially manufactures, uses, offers to sell, sells, or imports any of the Synthon Generic Product, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

92. Synthon Holding is jointly and severally liable for any infringement of the '703 patent. Upon information and belief, Synthon Holding participated in, contributed to, aided, abetted and/or induced Synthon Labs' submission of ANDA No. 90-047 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

93. Synthon Holding's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 90-047 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Synthon Holding commercially manufactures, uses, offers to sell, sells, or imports any of the Synthon Generic Product, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

94. Synthon is jointly and severally liable for any infringement of the '703 patent. Upon information and belief, Synthon participated in, contributed to, aided, abetted and/or induced Synthon Labs' submission of ANDA No. 90-047 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

95. Synthon's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 90-047 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover,

if Synthon commercially manufactures, uses, offers to sell, sells, or imports any of the Synthon Generic Product, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

96. Synthon Pharma is jointly and severally liable for any infringement of the '703 patent. Upon information and belief, Synthon Pharma participated in, contributed to, aided, abetted and/or induced Synthon Labs' submission of ANDA No. 90-047 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

97. Synthon Pharma's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 90-047 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Synthon Pharma commercially manufactures, uses, offers to sell, sells, or imports any of the Synthon Generic Product, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

98. Synthon Holding, Synthon, Synthon Labs, and Synthon Pharma were aware of the '703 patent prior to filing ANDA No. 90-047.

99. Synthon Holding's, Synthon's, Synthon Labs', and Synthon Pharma's actions render this an exceptional case under 35 U.S.C. § 285.

100. Plaintiffs will be irreparably harmed by Synthon Holding's, Synthon's, Synthon Labs', and Synthon Pharma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiffs pray for judgment as follows:

A. That all Defendants have infringed the '703 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' respective ANDAs identified in this Complaint shall not be earlier than the expiration date of the '703 patent, including any extensions;

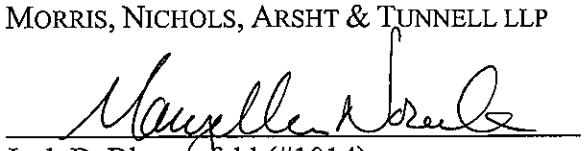
C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing any of the proposed generic versions of Plaintiffs' Namenda® brand product identified in this Complaint and any other product that infringes or induces or contributes to the infringement of the '703 patent, prior to the expiration of the '703 patent, including any extensions;

D. That this case is exceptional under 35 U.S.C. § 285;

E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

*Attorneys for Plaintiffs*

*Of Counsel:*

John Desmarais
Gerald J. Flattmann, Jr.
Melanie R. Rupert
KIRKLAND & ELLIS LLP
Citigroup Center
153 East 53rd Street
New York, NY 10022
(212) 446-4800

F. Dominic Cerrito
Daniel L. Malone
Eric C. Stops
JONES DAY
222 East 41st Street
New York, NY 10017
(212) 326-3939

February 15, 2008

**CERTIFICATE OF SERVICE**

I hereby certify that on February 15, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:.

Richard L. Horwitz, Esquire
David E. Moore, Esquire
POTTER ANDERSON & CORROON LLP

I further certify that I caused to be served copies of the foregoing document on February 15, 2008 upon the following in the manner indicated:

Richard L. Horwitz, Esquire
David E. Moore, Esquire
POTTER ANDERSON & CORROON LLP
1313 North Market Street – 6th Floor
Wilmington, DE 19801
*Attorneys for Interpharm Holdings, Inc. and Interpharm, Inc.*

*VIA ELECTRONIC MAIL and HAND DELIVERY*

Louis H. Weinstein, Esquire
BUDD LARNER, P.C.
150 John F. Kennedy Parkway
Short Hills, NJ 07078-2703
*Attorney for Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Limited*

*VIA ELECTRONIC MAIL and FEDERAL EXPRESS*

William Zimmerman, Esquire
Knobbe Martens Olson & Bear LLP
2040 Main Street
14th Floor
Irvine, CA 92614-3641
*Attorneys for Ranbaxy Inc. and Ranbaxy Laboratories Limited*

*VIA ELECTRONIC MAIL and FEDERAL EXPRESS*

Kendle International, Inc.
441 Vine Street
Cincinnati, OH 45202

*VIA FIRST CLASS MAIL*

James F. Hurst, Esquire
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, IL 60601
*Attorneys for Sun India Pharmaceutical Industries Limited*

*VIA ELECTRONIC MAIL and FEDERAL EXPRESS*

Jeffrey A. Hovden, Esquire
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151
*Attorneys for Genpharm, L.P., Genpharm Inc. and Mylan Pharmaceuticals Inc.*

*VIA ELECTRONIC MAIL and FEDERAL EXPRESS*

Maryellen Noreika (#3208)